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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,908	12/18/2006	Amar Lulla	PAC/23361 US (4137-00700)	9899

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EXAMINER	
PURDY, KYLE A	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
06/22/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,908	LULLA ET AL.	
	Examiner	Art Unit	
	K P	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-16* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of t/e previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/24/2010 has been entered.

Status of Application

2. The Examiner acknowledges receipt of the arguments filed on 8/24/2010.

3. Claims 1-7 and 10-16 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 8/24/2010 regarding the rejection of claims 1-7 and 10-16 made by the Examiner under 35 USC 103(a) over Wain (WO 0045795) in view of Foldvari (PSST, 2000) have been fully considered but they are not found persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 4/30/2010.

5. In regards to the 103(a) rejection, Applicant asserts the following:

A) Wain does not teach the feature of the composition comprising about 70% ethanol. Moreover, Page 3 of Wain teaches away from using more than 70% ethanol as Wain states that "the compositions [disclosed therein] will contain at most about 60% ethanol."

6. In response to A, it is acknowledges that Wain states that their compositions will contain at most about 60% ethanol. However, this is for their compositions "in general". It's the position of the Examiner that Wain's recitation of "in general" allows for composition which may

comprise more than their preferred 60% by weight of ethanol. Thus, while a composition comprising more than 60% ethanol may not have been preferred, one in possession of Wain would have identified a composition comprising a vehicle of at least 70% of ethanol as a viable vehicle for carrying and delivering the transdermal spray formulation. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. See MPEP 2123(II). Moreover, the use of patents as reference is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, and are relevant for all that they contain. See MPEP 2123(I).

Claim Objections

7. Claims 16 is objected to because of the following informalities: claim 16 recites, "wherein the optional penetration enhancer, when present, is different to ethanol". This should be changed to different "from" or "than" ethanol.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wain et al. (WO 00/45795; of record, see IDS) in view of Foldvari (PSTT, 2000, 3(12), 417-425).**

10. Wain is drawn to a topical medicinal spray composition which comprises one or medicaments in a non-aqueous vehicle and one or more film forming polymers (see abstract). The spray is to comprise one or more medicaments from about 0.1% to 25% by weight wherein the medicament may be a steroid such as estradiol and/or testosterone (see page 5, 2nd paragraph). Example 12 discloses a sample spray formulation which comprises the pharmaceutically active agent estradiol at a concentration of 1 % w/w, the film forming polymers PVP-VA (i.e. polyvinylpyrrolidone-vinyl acetate copolymer, VP/VA, see STN search results) at a concentration of 4 % w/w, the anti-nucleating agent PVP K-30 (polyvinylpyrrolidone, see STN search results) at a concentration of 6 % w/w and 83% of a non-aqueous vehicle (solvent component) (acetone + methylene chloride + ethanol). Claim 3 of Wain teaches the solvent (vehicle) may be present in an amount up to 90% wherein the vehicle is defined as non-aqueous solvent, wherein said solvent is preferably acetone, isopropyl alcohol, methylene chloride, methyl-ethylketone, absolute alcohol, ethyl acetate, trichloromonofluoromethane or methylene dimethyl ether (see claim 18). Thus, it would have been obvious to use at least 70% by weight ethanol in a transdermal spray formulation as Wain teaches that the solvent vehicles can be used and interchanged. The composition of Example 12 also comprises polyethylene glycol 6000 and polyethylene glycol at a concentration of 2 % and 3 % w/w/, respectively for a total of 5%. It is taught in the specification of Wain that polyethylene glycols are polyhydric alcohols, which in turn are skin permeation enhancers (see page 7, 5th paragraph and page 8, 3rd paragraph).

11. Wain fails to teach transdermal permeation enhancers as being selected from menthol, dimethylisosorbide, glycerylmonooleate and myristyl lactate.

12. Foldvari is a review article drawn to non-invasive administration of drugs through the skin. It is taught that menthol (terpene) is a useful penetration enhancer which acts by disrupting intercellular lipid orders (see instant claim 7). Moreover, addition of menthol to skin increases net electrical conductivity which indicates the opening of polar pathways in the stratum corneum and allows for simplifying the passage of active agents (see Table 1, page 420).

13. Therefore, one ordinarily skilled in the art, at the invention was made would be motivated to modify the teaching of Wain such that the transdermal spray formulation (particularly that of Example 12) comprising 1% w/w estradiol (a pharmaceutically active agent), between 0.1% to about 5.0% VP-VA copolymer, at least 70% of ethanol and permeation enhancer, wherein the permeation enhancer is selected from one of menthol, dimethylisosorbide, glycerylmonooleate and myristyl lactate, as taught by Foldvari, with a reasonable expectation in providing improved topical permeation benefit to the composition of Wain. As Wain suggests using a penetration enhancer in their composition, it follows that employing any penetration enhancer would be useful so long as it fulfills the role of performing its function, i.e. improved drug movement across skin barrier. With respect to the amount of ethanol in the composition being at least 70% by weight, this is also obvious. First, Wain teaches that the vehicle (ethanol) comprise up to 90% by weight of the spray composition. Second, the Examples of Wain (see Example 12, for instance) use three different solvents (acetone + ethanol + methylene chloride) in an amount of 83%, all of which are taught as useful/functionally similar solvents for carrying the composition. It would not have been innovative to substitute out methylene chloride and acetone for ethanol

and arrive at a composition comprising 83% of ethanol. Such a modification would have been obvious and any person of ordinary skill and common sense could have performed such with a reasonable expectation for success in arriving at a composition with excellent evaporative/delivery properties. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K P/
Examiner, Art Unit 1611
June 16, 2011

/Allison M. Ford/
Primary Examiner, Art Unit 1653